

**§ 52e.1**

52e.7 What are the terms and conditions of awards?

52e.8 Other HHS regulations and policies that apply.

52e.9 Additional conditions.

AUTHORITY: 42 U.S.C. 216, 285b–1.

SOURCE: 45 FR 12249, Feb. 25, 1980, unless otherwise noted.

**§ 52e.1 To what programs do these regulations apply?**

(a) This part applies to grants under section 419 of the Act (42 U.S.C. 285b–1) for projects to:

(1) Demonstrate and evaluate the effectiveness of new techniques or procedures for the prevention and control of heart, blood vessel, lung, and blood diseases, with special consideration given to the prevention and control of these diseases in children, and in populations that are at increased risk with respect to such diseases;

(2) Develop and evaluate methods of educating health practitioners concerning the prevention and control of these diseases; and

(3) Develop and evaluate methods of educating the public concerning the prevention and control of these diseases.

(b) For purposes of this part, prevention and control projects shall include community-based and population-based programs carried out in cooperation with other Federal agencies, with public health agencies of State or local governments, with nonprofit private entities that are community-based health agencies, or with other appropriate public or nonprofit private entities.

[45 FR 12249, Feb. 25, 1980; 45 FR 20097, Mar. 27, 1980, as amended at 58 FR 54298, Oct. 21, 1993; 59 FR 59372, Nov. 17, 1994]

**§ 52e.2 Definitions.**

As used in this part:

*Act* means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*).

*Council* means the National Heart, Lung, and Blood Advisory Council, established under section 406 of the Act (42 U.S.C. 284a).

*Director* means the Director of the National Heart, Lung, and Blood Institute and any official to whom the authority involved may be delegated.

*Emergency medical services* means the services utilized in responding to the perceived individual need for immediate medical care in order to prevent loss of life or aggravation of physiological or psychological illness or injury.

*HHS* means the Department of Health and Human Services.

*National program* means the National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program referred to in section 421 of the Act (42 U.S.C. 285b–3).

*Nonprofit* as applied to any agency or institution means an agency or institution which is a corporation or an association, no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

*PHS* means the Public Health Service.

[58 FR 54298, Oct. 21, 1993]

**§ 52e.3 Who is eligible to apply?**

To be eligible for a grant under this part, an applicant must be a public or nonprofit private agency or institution.

[45 FR 12249, Feb. 25, 1980, as amended at 58 FR 54298, Oct. 21, 1993]

**§ 52e.4 How to apply.**

(a) Application for a grant under this subpart shall be made on an authorized form.<sup>2</sup> Applicants shall submit completed forms on or before the dates the Director may prescribe.

(b) Each private institution which does not already have on file with the National Institutes of Health evidence of nonprofit status, must submit with its application acceptable proof of such status.

(c) In addition to any other pertinent information that the Director may require each application shall set forth in detail:

(1) The nature and purpose of the proposed project and the methods to be employed in carrying it out;

<sup>2</sup>Applications and instructions are available from the Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20205.

(2) The relevance of the proposed project to the National Program;

(3) The defined population to participate in the proposed project and the rationale for its selection;

(4) With respect to applications relating to projects covered by § 52e.1(a)(1), prior research findings on which the proposed project is based;

(5) The personnel, facilities, and other resources, including community resources, available to carry out the proposed project;

(6) Current activities of the applicant involving prevention or control of heart, blood vessel, lung, and blood diseases, the sources of funding for such activities, and the anticipated relationship of these activities to the proposed project;

(7) The names and qualifications of the project director and key staff members who would be responsible for conducting the proposed project;

(8) Proposed methods for monitoring and evaluating the project; and

(9) The proposed project period; a detailed budget for the first budget period, including a list of other anticipated sources of support and anticipated total needs for each of the succeeding budget periods of the requested project period; and a justification for the amount of grant funds requested.

[45 FR 12249, Feb. 25, 1980, as amended at 58 FR 54298, Oct. 21, 1993]

#### **§ 52e.5 What are the project requirements?**

(a) An approvable application must demonstrate to the satisfaction of the Director that:

(1) With respect to applications relating to projects covered by § 52e.1(a)(1), the techniques or procedures to be demonstrated and evaluated have been found safe and effective in the research setting and, based upon research findings, appear to have the potential for general applicability to the prevention, diagnosis, or treatment of heart, blood vessel, lung, or blood diseases;

(2) With respect to applications relating to projects covered by § 52e.1(a)(2) and § 52e.1(a)(3), the project will include development and evaluation of one or more methods for educating health practitioners or the public concerning

advances in the prevention, diagnosis, or treatment of such diseases; and

(3) The nature of the project is such that its completion may be anticipated within the project period, or such other period as may be specified in the application.

(b) The project must, in the judgment of the Director, be necessary for cooperation by the National Heart, Lung, and Blood Institute with one or more other Federal Health agencies, State, local or regional public health agencies, or nonprofit private health agencies in the diagnosis, prevention, or treatment of heart, blood vessel, lung or blood diseases.

[45 FR 12249, Feb. 25, 1980, as amended at 58 FR 54298 and 54299, Oct. 21, 1993]

#### **§ 52e.6 How will NIH evaluate applications?**

(a) Within the limits of funds available, after consultation with the Council, the Director may award grants to applicants with proposed projects which in the Director's judgment will best promote the purposes of section 419 of the Act, taking into consideration among other pertinent factors:

(1) The scientific and technical merit of the proposed project;

(2) The significance of the project in relation to the goals of the National Program;

(3) Whether the project appropriately emphasizes the prevention, diagnosis, or treatment of heart, blood vessel, lung, or blood diseases of children;

(4) The qualifications and experience of the project director and other key personnel;

(5) The administrative and managerial capability and fiscal responsibility of the applicant;

(6) The reasonableness of the proposed budget in relation to the proposed project;

(7) The adequacy of the methods proposed for monitoring and evaluating the proposed project; and

(8) The degree to which the application adequately provides for the requirements set forth in §§ 52e.5(a) and 52e.5(b).

(b) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompet for funds. This period,